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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,958	09/24/2003	Mark Alan Heldreth	265280-73424	4779

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INDIANAPOLIS, IN 46204

EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,958

Applicant(s)

HELDRETH, MARK ALAN

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/6/04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 9, 13, 14, 17, 20 and 26-31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pub. 2001/0037064 to Shahidi. Shahidi discloses a surgical system and method comprising a surgical burr (paragraph 28), a surgical navigation system, a processor, which is inherently electrically coupled to the burr, a navigation system, and a ROM or RAM memory device with instructions (paragraph 41). The memory device is used to determine the position of the burr and generate an output signal to adjust operation of the burr (paragraphs 18 and 38-40). By virtue of adjusting the position of the burr, a visual cue is signaled to the user. As a burr passes from tissue of one type to another (i.e. from soft tissue to hard tissue) the sound of the burr will inherently change because the different materials will resist the burr differently. The position of the burr is related to an anatomical feature. A boundary around an anatomical feature is inherently related thereto.

Fig. 5 further discloses a controller 24. An endoscope is used to generate image signals "indicative of the view along the axis of the instrument... which renders on the display an image of the patient's target site" (paragraph 46). This image can be used to determine the position of the burr relative to a known anatomical structure.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-4, 7, 8, 10-12, 15, 16, 19 and 21-25 are rejected under 35 U.S.C. 103(c) as being unpatentable over Shahidi in view of U.S. Patent No. 5, 269,785. Shahidi fails to disclose adjusting the speed of the burr. Nevertheless, Bonutti teaches adjusting the speed of the drill, "based on the need for the tissue removed." Moreover, dental drills are adjusted "on the fly," according to the will of the dentist, in order to cut hard tissue as needed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device alter the speed of the device (both increasing and decreasing), as taught by Bonutti and as is known in the art of dental drilling. Furthermore, it would have been obvious to modulate the burr speed

in response to an output signal, as determined by the instructions, in order to automatically modulate the burr speed when passing from one type of tissue to another.

Claims 1, 2, 5, 6, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti. Bonutti discloses a method of operating a surgical burr (the burr is indicated in col. 7, lines 52-53). The user performs the method, rather than a hardware system. To explain this further, a surgeon determines the position of the burr by sight. The brain sends a signal to the hand in response to the determined position to adjust the position of the burr as needed.

Bonutti falls short of disclosing that the burr speed may be adjusted in response to the output signal. Nevertheless, col. 2, lines 44-46 disclose that the drill/burr requires a different speed when cutting through different tissue. When a surgeon passes the drill from one type of tissue to another, a burr speed adjustment would be helpful if not required. For example, it would be helpful to change the burr speed when passing from cortical to cancellous bone, which would more efficiently be done "on the fly," rather than removing the drill, changing the drill speed and replacing the drill. After all, dental drills are known to change speed "on the fly." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the speed of the drill when passing from one tissue to another in order to quickly accommodate the different tissue.

The tissue border or anatomical feature, acts as a boundary signaling to the using that a modulation in drill speed is necessary. It would have been obvious to one

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of ordinary skill in the art to either increase or decrease the drill speed as required by the predetermined boundary tissue in order to accommodate the change in tissue.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD
May 3, 2004


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700